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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
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ART UNIT	PAPER NUMBER
3736	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/643,006	LOVETT ET AL.	
	Examiner	Art Unit	
	HELEN NGUYEN	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 May 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *89-93,95-110 and 112-123* is/are pending in the application.

4a) Of the above claim(s) *90,100,108,110 and 120* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *86-89,91-93,95-99,101-107,109,112-119 and 121-123* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 5/4/2010 has been entered.

2. Claims86, 88, 92, 93, 97, 98, 104, 106, 110, 114, 116, and 117 are amended. Claims 94 and 111 are cancelled. Claims 90, 100, 108, 110, and 120 are withdrawn from consideration. **Claims 86-89, 91-93, 95-99, 101-107, 109, 112-119, and 121-123** remain pending and under prosecution.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. **Claims 86, 88-89, 91-93, 95-99, 101, 104, 106-107, 109, 112-117, and 121** are rejected under 35 U.S.C. 103(a) as being unpatentable over Verrier et al (US Pat No. 5902250) in view of Cho et al (US Pub No. 20050119711), further in view of Young (US Pub No. 20030083241).

5. In regard to **Claims 86, 89, 91, and 104**, Verrier et al disclose a method and apparatus for classifying sleep states comprising:

a detector system comprising sensors 12, 14 for detecting conditions related to sleep, the sleep-related conditions comprising a condition associated with a sleep-wake status of a patient such as patient activity or head movement (Col.5: 34-35) and a condition associated with REM sleep such as eyelid movement (Col.11: 29-35);

a classification system 34 for classifying one or more sleep states based on the detected conditions of REM sleep and sleep-wake status (Col.8: 39-41).

6. However, Verrier et al do not disclose classifying the one or more sleep states is performed at least in part implantably and does not disclose providing sleep state informed therapy. Verrier et al also do not disclose the first sensor is disposed on a cardiac rhythm management device which is implanted. It is noted that Verrier et al do disclose the invention also used for monitoring breathing patterns and heart function for the detection of sleep-related conditions (col.12-13). Cho et al disclose an effective implantable cardiac rhythm management device for the detection of sleep-related breathing conditions to provide the advantages of constant monitoring without the disadvantages associated with user-related use (¶0010). Cho et al also teach that the implantable device for detecting sleep-related conditions provides therapy (¶0016) to effectively treat the patient when certain conditions are detected. Cho et al also disclose a sensor 62 disposed on at least a portion of the implanted cardiac rhythm management device (¶0043-0044, also see 0016, 0032-0033).

7. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to make the invention of Verrier et al perform the classifying of one or more

sleep states at least in part implantably using a cardiac rhythm management device with a sensor disposed on it as taught by Cho et al to improve the invention by allowing constant monitoring without requiring user involvement for use. It would also have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Verrier et al and Cho et al to provide sleep state informed therapy such as respiratory or cardiac therapy as taught by Cho et al to effectively treat the patient when respiratory or cardiac sleep-related conditions are detected.

8. However, Verrier et al and Cho et al do not disclose the condition associated with REM-sleep comprises sensing a muscle tone in a pectoral region of the patient using the first sensor above. Young teaches that sensing a muscle tone in a pectoral region is a positive sign of REM-sleep which is typically accompanied by muscle atonia in that region (¶0047). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the REM sensed condition of Verrier et al as modified by Cho et al with that of sensing a muscle tone in a pectoral region of the patient as taught by Young, wherein it is well known within the art that muscle tone is measured using a sensor, as an equally as effective means to determine the onset of REM-sleep implantably.

9. In regard to **Claims 88, 106-107, and 109**, Verrier et al in combination with Cho et al and Young disclose sensing muscle tone using a sensor mechanically coupled to an implantable medical device adapted for implantation in the pectoral region of the patient, wherein the position of the sensor as mounted on the housing is considered a header (see Cho ¶0032 – pacemakers or ICDs).

10. In regard to **Claims 92 and 112**, Verrier et al in combination with Cho et al and Young disclose the method and apparatus for detecting the sleep-wake status of the patient by patient activity through sensor 14 but do not specifically disclose detecting the sleep-wake status using an accelerometer. However, Verrier et al do disclose that any suitable sensor for detecting movement can be used in place of sensor 14 (Col.7: 18-20). Because it is widely known that an accelerometer detects movement, it would have been obvious to one of ordinary skill in the art at the time the invention was made to detect the sleep-wake status of the patient using an accelerometer as an equally as effective sensor for detecting the patient activity and thus sleep-wake status.

11. In regard to **Claims 93 and 113**, Cho et al disclose detecting the conditions related to sleep comprises detecting body posture or torso orientation (¶0045).

12. In regards to **Claims 95-98 and 114-117**, Verrier et al in combination with Cho et al and Young disclose the sleep-wake status includes a patient activity signal, and wherein classifying includes determining sleep onset or offset by comparing the patient activity signal to a sleep threshold, as well as determining REM sleep onset or offset by necessarily comparing the pectoral muscle tone or lack thereof – atonia – to an REM sleep threshold (Verrier et al Col.9: 31-Col.11: 35).

13. In regard to **Claims 101 and 121**, Verrier et al in combination with Cho et al and Young disclose detecting a cardiac signal and analyzing with an analyzer 34 the cardiac signal on a beat

to beat basis (Verrier et al Col.8: 25-Col.10), wherein the therapy system of Cho et al is naturally configured to provide therapy based on both the sleep state classification and the beat to beat cardiac signal analysis for the reasons elaborated above (Verrier et al Col.9: 60-67, Col.12-13).

14. **Claims 87 and 105** are rejected under 35 U.S.C. 103(a) as being unpatentable over Verrier et al in view of Cho et al and Young, further in view of Hendricks et al (US Pat No. 6387907).

15. Verrier et al in combination with Cho et al and Young disclose classifying REM sleep but do not disclose doing so by sensing muscle tone using an electromyogram sensor. Hendricks et al teach that REM is characterized by the lack of muscle tone, which can be determined through EMG activity (Col.10: 53-61). Since it is well known in the art that an electromyogram sensor senses EMG activity, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Verrier et al, Cho et al, and Young to sense REM sleep through muscle tone using an electromyogram sensor as taught by Hendricks et al as an equally as effective means of classifying REM sleep.

16. **Claims 99 and 118-119** are rejected under 35 U.S.C. 103(a) as being unpatentable over Verrier et al in view of Cho et al and Young, further in view of Tchou et al (US Pat No. 6572557).

17. Verrier et al in combination with Cho et al and Young disclose the invention above but do not explicitly disclose providing bradycardia pacing therapy. Tchou et al teach effectively providing bradycardia therapy in the presence of the specific arrhythmia (Col.7: 37-54). Since

Verrier et al already disclose the detection of heart arrhythmias (Col.12: 2-41) and Cho et al teach the advantages of providing therapy as elaborated above, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Verrier et al as modified by Cho et al and Young in the manner above, to provide bradycardia pacing therapy as taught by Tchou et al in response to a detected cardiac signal indicating the condition, wherein it would have also been obvious to switch to a lower pacing rate based on the sleep state classification because it is known in the art that for example a higher pacing rate may awaken the patient and therefore a lower pacing rater would be desired if the patient is found to be in a sleep condition (Cho et al ¶0008).

18. **Claims 102-103 and 122-123** rejected under 35 U.S.C. 103(a) as being unpatentable over Verrier et al in view of Cho et al and Young, further in view of Mathews et al (US Pub No. 20030111079), further in view of Cobb (US Pub No. 20040249299).

19. Verrier et al in combination with Cho et al and Young disclose the invention above but do not explicitly disclose declaring a hypopnea event if a detected tidal volume falls below a hypopnea threshold. Mathews et al teach that a hypopnea event is determined by comparing tidal volume against a hypopnea threshold, wherein a hypopnea event is determined when the tidal volume falls below, i.e. does not fall on, the threshold (¶0277). Further, Cobb teaches that hypopnea is recognized as falling between normal baseline values and an apneic threshold, i.e. an apnea threshold is lower than a hypopnea threshold (¶0115). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Verrier et al as modified by Cho et al and Young in the manner above, to declare a

hypopnea event if a detected tidal volume falls below a hypopnea threshold as taught by Mathews et al and to also declare an apnea event if the tidal volume falls below an apnea threshold lower than the hypopnea threshold as taught by Cobb to effectively determine the presence of either hypopnea or apnea and subsequently provide the appropriate therapy.

Response to Arguments

20. Applicant's arguments filed 5/4/2010 have been fully considered but they are not persuasive. Applicant contends that Verrier et al, Cho et al, and Young do not disclose sensing muscle tone in a pectoral region of a patient using a sensor disposed on a cardiac rhythm management device and detecting REM sleep status based on the sensed pectoral muscle tone. However, it is respectfully maintained that the combination of references does indeed disclose that. Verrier et al teaches detecting REM sleep to determine sleep classification, Cho et al teach an analogous device which is a cardiac rhythm management device implanted within the pectoral region of a patient with a sensor disposed thereon, and Young teaches sensing muscle tone or lack thereof – atonia – in a pectoral region of a patient to determine REM sleep status. Therefore, it is maintained that the combination of at least Verrier et al, Cho et al, and Young as motivated by the reasons elaborated above disclose the invention claimed.

Conclusion

21. All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under

37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HELEN NGUYEN whose telephone number is (571)272-8340. The examiner can normally be reached on Monday - Friday, 9 am - 6 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/H. N./
Examiner, Art Unit 3736

/Max Hindenburg/
Supervisory Patent Examiner, Art Unit 3736